

**Remarks**

The Final Office Action mailed October 15, 2004 has been received and reviewed. Claims 54, 61, and 85 having been amended herein, and claims 58, 62, 64, 66-67, 72-76, 79-84, and 86-107 having been canceled herein, the pending claims are claims 54-57, 59-61, 63, 65, 68-71, and 85. Reconsideration and withdrawal of the rejections are respectfully requested.

The amendments to claim 54 are supported, for example, by the specification at page 45, line 22 to page 47, line 5; Figure 1; and originally filed claim 64. The amendment to claim 61 is supported by originally filed claim 62, now canceled. Claim 85 has been amended by rewriting it in independent form.

**Interview Summary**

Applicants thank Examiner David J. Steadman for granting a telephonic interview with Applicants' Representative, Loren D. Albin, on January 25, 2005. It was noted that claim 85, drawn to a crystal, has only been provisionally rejected under obviousness-type double patenting, and would be in condition for allowance if rewritten in independent form. Corresponding method of making claims were also discussed, and Applicants thank the Examiner for agreeing to consider new claims drawn to a method of making a crystal as recited in claim 85.

**Provisional Statutory-Type Double Patenting Rejection**

The Examiner provisionally rejected under 35 U.S.C. §101, claims 54-71 as claiming the same invention as that of claims 1-18 of copending Application Serial No. 10/027,277; and claims 54, 56, and 72-76 as claiming the same invention as that of claims 4, 5, and 24-28 of copending Application Serial No. 10/144,441.

Claims 54 and 61 having been amended, and claims 58, 62, 64, and 66-67 having been canceled, Applicants respectfully submit that the rejection has been rendered moot. However, in the event that the provisional statutory-type double patenting rejections are maintained, and are

the only rejections remaining in the present application, the Examiner is respectfully requested to withdraw the provisional statutory-type double patenting rejection and allow the present application to issue as a patent pursuant to M.P.E.P. §822.01.

Reconsideration and withdrawal of the rejections are respectfully requested.

### **Provisional Obviousness-Type Double Patenting Rejection**

The Examiner maintained the obviousness-type provisional double patenting rejection of claims 54, 55, and 57-71 as being unpatentable over claims 1-3 and 6-23 of copending Application Serial No. 10/144,441; claims 54-69 as being unpatentable over claims 7-23 of copending Application Serial No. 10/143,502; and claims 54-67 as being unpatentable over claims 12-26 of copending Application Serial No. 10/143,723. The Examiner rejected under the judicially created doctrine of obviousness-type double patenting, claims 93-100 as being unpatentable over claim 1 of copending Application Serial No. 10/027,277; and claims 79-90 as being unpatentable over claims 27-28 of co-pending Application Serial No. 10/144,441.

Claims 54, 61, and 85 having been amended, and claims 58, 62, 64, 66-67, 86-90, and 93-100 having been canceled, Applicants respectfully submit that the rejections have been rendered moot. However, in the event that the provisional obviousness-type double patenting rejections are maintained, and are the only rejections remaining in the present application, the Examiner is respectfully requested to withdraw the provisional obviousness-type double patenting rejection and allow the present application to issue as a patent pursuant to M.P.E.P. §822.01.

### **Rejection under 35 U.S.C. §112, Second Paragraph**

The Examiner rejected claims 83, 86-87, 90, 93-100, 103, and 105-107 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully disagree. However, in the interest of expediting the prosecution of the present application,

claims 83, 86-87, 90, 93-100, 103, and 105-107 have been canceled, and the rejection has been rendered moot.

Reconsideration and withdrawal of the rejection are respectfully requested.

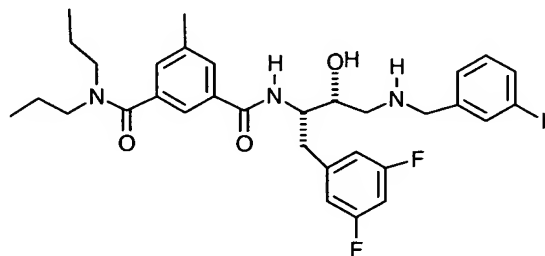
**Rejections under 35 U.S.C. §112, First Paragraph**

***Written Description***

The Examiner rejected claims 86, 90, 95-96, 99-100, 103, and 105-107 under 35 U.S.C. §112, first paragraph, as a new matter rejection. Applicants respectfully disagree. However, in the interest of expediting the prosecution of the present application, claims 86, 90, 95-96, 99-100, 103, and 105-107 have been canceled, and the rejection has been rendered moot.

The Examiner also rejected claims 54-76, 79-82, 84, 88, 91-93, 95, 97, 99, and 101-107 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 54 and 61 have been amended, and claims 58, 62, 64, 66-67, 72-76, 79-82, 84, 88, 91-93, 95, 97, 99, and 101-107 have been canceled. However, to the extent that the rejection still applies to claims 54-57, 59-61, 63, 65, and 68-71 (as amended), Applicants respectfully traverse the rejection.

The Examiner alleged that the disclosed species of beta secretase and the disclosed species of inhibitor did not support the claimed genus. Independent claim 54 has been amended herein to recite the species of human beta secretase having amino acid sequence SEQ ID NO:1 and the species of inhibitor wherein the inhibitor is



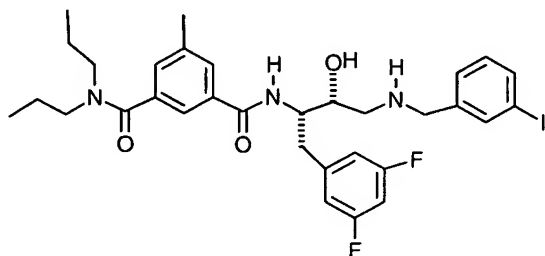
Thus, Applicants respectfully submit that the rejection has been rendered moot.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph, are respectfully requested.

*Enablement*

The Examiner rejected claims 54-76, 79-84, and 86-107 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In the interest of expediting the prosecution of the present application, claims 54 and 61 have been amended, and claims 58, 62, 64, 66-67, 72-76, 79-84, and 86-107 have been canceled. To the extent the rejection still applies to claims 54-57, 59-61, 63, 65, and 68-71 (as amended), Applicants respectfully traverse the rejection.

Specifically, the Examiner alleged that the scope of the rejected claims is not reasonably enabled by the specification. Independent claim 54 has been amended herein to recite the species of human beta secretase having amino acid sequence SEQ ID NO:1 at a concentration of about 1 mg/ml to about 80 mg/ml; and the species of inhibitor wherein the inhibitor is



Further claim 54 recites preparing human beta secretase at a concentration of about 1 mg/ml to about 80 mg/ml; and crystallizing the human beta secretase from a solution comprising about 17% by weight to about 22% by weight PEG 3000, and having a pH of about 3.5 to about 5.5. Thus, Applicants respectfully submit that claim 54 (as amended), and claims 55-57, 59-61, 63, 65, and 68-71, which depend therefrom, are reasonably enabled by the specification.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph, are respectfully requested.

Serial No.: 10/028,224

Confirmation No.: 4497

Filed: December 21, 2001

For: CRYSTALLIZATION AND STRUCTURE DETERMINATION OF GLYCOSYLATED HUMAN BETA  
SECRETASE, AN ENZYME IMPLICATED IN ALZHEIMER'S DISEASE

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**Summary**

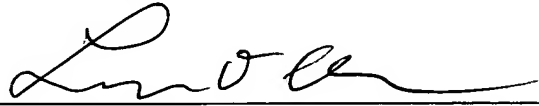
It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for  
**Benson et al.**

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February 15, 2005

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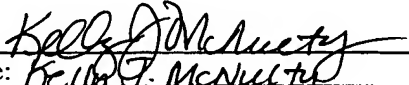
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